

Appendix A

Detailed Evaluation of ABAR-W375-00-00010

Alignment of ISMP and SRD with QAPIP

The purpose of this appendix is to document the detailed examination of the changes proposed by ABAR-00-00010 and the rationale for acceptance or rejection of the changes. The appendix is organized by individual change, beginning with the proposed changes to the Safety Requirements Document (SRD). The criteria associated with Quality Assurance (QA - i.e., SRD Criteria 7.3-1 through 7.3-12) are individually examined. An analysis of changes to the text of the Integrated Safety Management Plan (ISMP) not related to SRD criteria changes follows.

The RU assessed the proposed change from ad hoc standards contained in the ISMP and ISA to use of DOE G-830.120 as a new implementing standard separately in the preceding Safety Evaluation Report, and rejected that change due to insufficient justification. That analysis is not included in this appendix. Therefore, the following analysis considers the effect of the changes proposed by BNFL independent of use of DOE G-830.120 as a new implementing standard.

Changes to the SRD

Safety Criterion 7.3-1

This criterion requires the application of quality assurance elements using a graded approach. BNFL proposes changes and deletions in the implementing standard, ISMP Section 1.3.11, "Quality Levels." The proposed changes to Section 1.3.11 are:

1. Changing wording from "Designation of correct quality levels ensures...." to "Designation of correct quality levels helps to ensure...."

This change is acceptable as it more correctly reflects the intent of using a classification process to assign quality assurance requirements based on safety significance.

2. Eliminating the reference to three quality levels. BNFL has added a fourth quality level associated with Commercial Grade Systems, Structures, and Components (SSCs).

This change is acceptable, as the number of quality levels used is not established by 10 CFR 830.120. This change is also consistent with the changes to the BNFL Quality Assurance Program and Implementation Plan (QAPIP) previously approved by the RU.

3. Deleting the text describing Quality Levels and referencing to the QAPIP. This includes deleting the associated Table 1.3.

This change is acceptable for the following reasons:

- The deleted text is identical to the text in QAPIP Section 1.3.1, "Classification of Items." Therefore, there is no diminution in the commitment.

- The deleted table is fully reproduced in the QAPIP as Appendix B, "Application of Quality Assurance Program Requirements for QL-1, QL-2, and QL-3 Structures, Systems, and Components." (Note that the table also describes the application for commercial grade items.) The RU previously approved the referenced table.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-2

This criterion requires the development, implementation, and maintenance of a Quality Assurance Program. The proposed changes in the implementing standard, ISMP Section 1.3.9 are:

1. A number of editorial changes (additions in italics), as follows:

- A change that the BNFL QAPIP is *submitted to and* approved by the DOE
- A revision to the currently approved version of the QAPIP and the RU letter of approval
- A change that the QAP requires periodic assessment of activities, *both by management and by knowledgeable, independent personnel as described in QAP sections 9 and 10.* (This change correctly cites the QAPIP.)
- An editorial change to restructure a sentence which clarifies and does not alter its meaning
- The following statement, which expands the linkage to the QAPIP: *The QAP also describes the process of qualifying personnel who perform assessments, audits, and surveillances, as well as documentation of results and review by management.*

These changes are acceptable, as they do not eliminate commitment; rather they expand the level of detail and linkage to the QAPIP.

2. The elimination of the following text:

"Assessment, audits, and surveillance are performed in accordance with procedures by qualified personnel. Results are documented and reviewed by management with responsibility in the areas being audited."

The approved QAPIP contains the following statements:

"Management assessments shall be performed and documented in accordance with written procedures. Results of management assessments shall be documented and reported to the assessed organization's management and senior management."

"Audits, assessments, and surveillances are as follows:
Led by appropriately qualified and certified audit personnel....
Conducted in accordance with approved procedures and documented in a report to appropriate management."

"Personnel that conduct assessments shall not be directly responsible for the work processes and systems being assessed, but shall be qualified and technically knowledgeable in the subject matter assessed."

A comparison of the continuing commitments in the QAPIP with the eliminated text shows that the level of commitment is not diminished by this deletion. Therefore, the proposed change is acceptable.

3. The elimination of the following text:

"The scope and details of the QAP are further discussed in the ISAR Chapter 3.3, Quality Assurance."

The deletion of this citation has several effects. In general, despite the apparent meaning of the eliminated statement, the QA-related text in the ISAR summarizes (this is, is less extensive than) the corresponding QAPIP text. However, this is not uniformly the case. In addition, ISAR Chapter 3.3 is neither a restatement of the QAPIP nor can the text be tracked directly from one document to the other. Rather, ISAR Chapter 3.3 appears to have been prepared largely independent of the QAPIP text - possibly by separate authors. While it contains the same general QA principles they are, in many cases, restated in different words and organized differently.

ISAR Chapter 3.3 contains some material that is related to safety rather than to QA and is therefore not traceable to the underlying QA requirements. The affect of this material is noted, as appropriate, in the following analysis. However, the analysis speaks only to a comparison of QA requirements. No analysis of the acceptability of safety-related commitments and potential differences among authorization basis documents was made and no acceptance of changes to the ISAR safety commitments can be implied from this analysis.

In order to evaluate the acceptability of the proposed change, it was necessary to individually compare the QA commitments in ISAR Chapter 3.3 against the commitments in the QAPIP. This analysis found that the documents were equivalent with the following exceptions:

- NUREG-1293: The ISAR cites NUREG-1293 as an applicable requirement. NUREG-1293 was eliminated as a contract requirement after the issuance of the ISAR and this was recognized in the current QAPIP. This difference is therefore acceptable.
- Commitment to RL/REG-96-01, Revision 0: The ISAR makes the following statement:

"BNFL Inc. is committed to establishing and implementing a QAP that meets all requirements (sic)...as identified in RL/REG-96-01, Revision 0, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*."

There is no equivalent commitment in the approved QAPIP. **Therefore, this change represents a decrease in commitment that is not addressed or justified by the BNFL submittal.** While RL/REG-96-01 is not intended to specify QA requirements, the RU has no objection to BNFL using the document for guidance. (Note: recently the RU modified and reissued RL/REG-96-01 as Revision 1. The contents of this revision are based on the requirements of the contract, the QA Rule and the content of G-830.120, "Implementation Guide for Use with 10 CFR Part 830.120." G-830.120 was not developed as a consensus standard. Rather it was developed by DOE contractors to provide guidance on the application of the QA rule. Likewise, RL/REG-96-01 is intended as guidance to reviewers and was not developed for use as a standard.)

Subordinate QA Plans: The ISAR makes the following statement:

"Each principal subcontractor is also required to establish and implement its own QAP for the TWRS-P Project.... BNFL Inc. reviews and approves the QAPs developed by the principal subcontractors."

The currently approved QAPIP makes the following statement:

"The QAP is applicable to project work performed by the functional groups and principal subcontractors performing work for the project, and is the single QA program for the Project. Subcontractors performing work for the project are required to work to the QAP. However, when subcontractors must perform work unique to their business, subcontractors are required to address the specific quality assurance program requirements specific to their work...and submit their plan to the QA Manager for approval before starting the work."

This difference reflects a change in approach by BNFL regarding how QA requirements are passed to contractors. The alternate approach is acceptable under the QA rule and was evaluated as such by the RU in its assessment of the currently approved QAPIP. The difference is therefore acceptable.

QA Manager stop work authority: The ISAR makes the following statement:

"The TWRS-P Project QA Manager and designated QA personnel...have the authority and the responsibility...to stop work in unsafe situations and to control further operation until the conditions that created the unsafe conditions are corrected."

The statement in the currently approved QAPIP is:

"The QA Manager...(h)as the authority and responsibility to stop project work when the work, if allowed to continue, would result in activities or documents being in noncompliance with stated requirements."

These statements are not equivalent. However, by procedure BNFL grants to all employees the authority and responsibility to stop work in unsafe situations (Procedure K13P051, "Authority to Stop Work - attached). The QAPIP speaks to the specific QA-related stop work authority of the QA Manager. The difference is therefore acceptable.

Training evaluation: The ISAR makes the following commitment:

"Management evaluates training program efficacy and efficiency through interviews, feedback from instructors, students, students' managers, and periodic reviews."

The QAPIP commits to:

"The QA Manager...(p)eriodically shall assess the status and effectiveness of the indoctrination and training programs to ensure that they continue to reflect the current systems, procedures, and policies applicable to each position. Assessments of the training program conducted by the QA Manager shall be coordinated with the Project Manager and shall be scheduled at least annually."

The approved QAPIP describes a Management Assessment Program (Part 9.0) but does not make a specific commitment to management evaluation of the training program. **This change represents a decrease in commitment that is not addressed or justified by the BNFL submittal.**

Training Requirements: The ISAR makes the following commitment:

"Qualification and training requirements for specific positions are based on a documented analysis of the specific duties and tasks associated with those positions."

The corresponding statement in the QAPIP is:

"Specific safety, quality and technical training shall be planned, scheduled, provided, and maintained for personnel in their respective disciplines as defined by position descriptions and specific work assignments."

These statements are equivalent except for the specific commitment to document the analysis. **This decrease in commitment is not addressed or justified in the BNFL ABAR submittal.**

Corrective Action: The ISAR makes the following commitment:

"The QA organization provides concurrence on the adequacy of the corrective actions(s), verifies implementation of the corrective action(s), and closes out the corrective action in a timely manner...."

The corresponding statement in the QAPIP is:

"The QA manager...(h)as the responsibility for reviewing for significant conditions adverse to quality and concurring with proposed corrective actions and the dispositions of nonconforming conditions, and for verification of completion of identified corrective actions."

The distinction between the two statements is that the latter applies only to significant conditions. For deficiencies falling in the classification of "adverse to quality," the QAPIP requires:

"[The condition] shall be documented, entered into the CAMS (Corrective Action Management System) and managed to disposition and closure...."

This commitment partially addresses the distinction between the two statements and is consistent with the guidelines of G-830.120. Therefore, while this change does represent a decrease in commitment, it is evaluated to be acceptable.

Design Review: The ISAR makes the following commitment:

"Design drawings and specifications for SSCs affecting quality are reviewed by the QA organization to ensure that the documents are prepared, reviewed, and approved in accordance with TWRS-P Project procedures and that the documents contain necessary QA requirements...."

The QAPIP makes the following statement:

"QA reviews are performed of selected design documents to ensure that appropriate quality requirements, QC inspection requirements and QA criteria are adequately specified."

The two statements are not equivalent and this change therefore represents a decrease in commitment that is not justified by the BNFL submittal.

- Procurement: The ISAR contains specifics regarding the content of procurement documents and procurement records that go beyond the detail in the QAPIP. This section (3.3.4.6) of the ISAR also contains supplemental detail on supplier assessment and on performance history evaluation. The information provided in this section is not inconsistent with the QAPIP, rather it is at a level of detail that would be more appropriate for an implementing procedure. As the level of detail in the QAPIP was evaluated and found to meet the guidance of G-830.120, this difference is acceptable.

In summary, some elements of eliminating the reference to ISAR Chapter 3.3 do represent an essential decrease in commitment.

Conclusion: The following elements of the proposed change are not justified by the BNFL ABAR submittal:

- Eliminating the requirement to meet the guidance of RL/REG-96-01
- Modifying the scope of the QA review of design documents
- Eliminating the requirement that the basis for training be documented
- Eliminating the specific requirement for management evaluation of training

All other elements of the proposed change are acceptable.

Safety Criterion 7.3-3

This criterion requires training to ensure personnel are capable of performing their assigned and job proficiency is maintained. The ABAR proposes no changes in the implementing standard, ISMP Section 3.15.

Conclusion: No analysis required.

Safety Criterion 7.3-4

This criterion addresses document control and records management. The proposed changes to ISMP Chapter 8.0 are:

1. Editorial changes to cite the current version of the QAPIP. These changes do not affect BNFL commitments.
2. Deletion of the following text:

"Details of the records management program are described in ISAR Section 3.8, 'Records Management'."

As noted in 7.3-2, above, in order to evaluate the acceptability of the proposed change, it was necessary to individually compare the QA commitments in ISAR Chapter 3.8 against the commitments in the QAPIP. This analysis found that the documents were equivalent with the following exceptions:

- Controlled Document List: The ISAR contains a three-page table of examples of records that are maintained by the records management system. The ISMP (Table 8.1) contains a corresponding list. An analysis of differences between the lists shows that the quality assurance portions are equivalent (identical except for minor wording differences). The other differences between the tables are primarily related to examples of environmental documentation, which appear in the ISAR but not in the ISMP and the addition of safety-related (primarily radiological) documents to the ISMP. Additionally, the QAPIP requires that:

"A master list shall be established to identify the current revision of controlled documents to preclude the use of non applicable or superseded documents."

As the lists are equivalent for QA, and BNFL has committed to maintain a master list, this change is acceptable. (Again, the acceptability of changes to the ISAR safety-related management records cannot be assumed or implied from this analysis.)

- Requirements for Records Storage Facilities: The ISAR specifies certain requirements for records storage facilities. The QAPIP does not specifically state these requirements, however, it does commit that the records retention and turnover requirements of ASME NQA-1 (1994) Supplement 17S-1, Supplementary Requirements for Quality Assurance Records," will be met. NQA-1 contains equivalent wording; therefore, the difference is acceptable.
- Supplier Records: The ISAR contains specifics regarding requirements for suppliers to maintain records that go beyond the detail in the QAPIP. The information provided in this section is not inconsistent with the QAPIP, rather it is at a level of detail that would be more appropriate for an implementing procedure. As the level of detail in the QAPIP was evaluated and found to meet the guidance of G-830.120, this difference is acceptable.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-5

This criterion addresses the control of work processes. The ABAR proposes no changes in the implementing standard, ISMP Section 1.3.11. BNFL does propose deleting the references to Section 1.3.11 (and Table 1-3; see Part 3 of Safety Criterion 7.3-1, above) in Section 1.3.10. As these changes are consistent with those analyzed above for Safety Criterion 7.3-1, and do not represent a diminution of commitment, they are acceptable.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-6

This criterion addresses quality improvement. The proposed changes to ISMP section 2.2, "Compliance with 10 CFR 830.120, *Quality Assurance Requirements*," are:

1. Editorial changes to cite the current version of the QAPIP. These changes do not affect BNFL commitments and are acceptable.
2. Elimination of the reference to ISAR Section 3.3, "Quality Assurance." As noted in part 3 of the analysis of Safety Criterion 7.3-2, eliminating this reference does represent a decrease in commitment that is not justified in the BNFL ABAR submittal.

Conclusion: The proposed changes are not acceptable.

Safety Criterion 7.3-7

This criterion addresses inspection and acceptance testing. The proposed changes are the same as those described in Safety Criterion 7.3-1, above.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-8

This criterion addresses management assessment. The proposed changes to ISMP Chapter 10.0, "Assessments" are limited to specifically citing QAPIP Section 9, "Management Assessment," and Section 10, "Independent Assessment" in the text. There are no proposed deletions.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-9

This criterion addresses independent assessment. The proposed changes are the same as those described in Safety Criterion 7.3-8, above.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-10

This criterion specifically addresses the performance of compliance audits. ISMP Chapter 8.0 and Section 5.4 are cited as implementing codes and standards. The analysis of BNFL-proposed changes to Chapter 8.0 is described in Safety Criterion 7.3-4, above. The changes were acceptable. BNFL proposes no changes to the implementing standard, ISMP text of Section 5.4, "Compliance Audits."

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-11

This criterion addresses procurement. ISMP Section 2.2 is cited as the implementing standard. This section simply references the QAPIP. The analysis of BNFL-proposed changes to Section 2.2 is described in Safety Criterion 7.3-6, above.

Conclusion: The proposed changes are acceptable.

Safety Criterion 7.3-12

This criterion requires the annual submittal of changes to the BNFL Quality Assurance Program. The changes are to be submitted to the regulator for review. BNFL proposes to delete the reference to ISMP Section 3.3.3 as the implementing standard. The RU concurs that this criterion must be implemented but does not need a separate implementing standard because it is, in itself, a direct statement of the requirement.

The RU notes that section 3.3.3 contains a commitment from BNFL regarding the submittal of changes to the QAP to the RU "for review and approval 30 days prior to the implementation of the subject changes." As BNFL has not proposed a change to this wording, the RU considers this commitment to remain in effect.

The RU notes that section 3.3.3 contains the wording "These annual updates are also subject to the 30-day prior review by the Regulatory Unit." The 10 CFR 830.120 requirement is "...QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date..." Accordingly, the RU has 90 days to approve or reject annual updates to the BNFL QA Plan after its submittal by BNFL.

BNFL proposes no changes to the text of Section 3.3.3, "Changes to the Authorization Basis."

Conclusion: The proposed change is acceptable.

Page B-10

This is an editorial change from a reference to a specific revision of the QAPIP to a reference to the current version and is acceptable.

Changes to the ISMP

Changes to List of Acronyms

The changes to Page viii of the ISMP are editorial and are acceptable.

Changes to Page 1-3

These changes are to correct document citations and are acceptable.

Changes to Page 1-25

There are two changes to this page. The first modifies text to reflect that Technical Safety Requirements do not currently exist. The second eliminates the reference to ISMP section 1.3.11 for defining Quality Levels (see the discussion under Safety Criterion 7.3-1, above).

Conclusion: The proposed changes are acceptable.

Changes to Page 3-7 and Page 3-13

There are two changes to page 3-7.

The first change (with an identical change proposed to page 3-13) deletes the specific requirement that the Quality Assurance Requirements and Description (QARD - DOE/RW/0333P) will be applied to "QL-1 and QL-2 items and activities associated with HLW services from design through production and acceptance." This commitment is replaced with

"...as described in the QAP." The QAPIP requires compliance with the "applicable elements" of the QARD and also states that:

"The provisions of the QARD shall be applied to QL-1 and QL-2 items and activities associated with IHLW services from product development through production, qualification, and acceptance.

The statements are not equivalent and the change is therefore not acceptable without justification by BNFL. It is acceptable to delete the statement from Section 3.5 of the ISMP since the first sentence of the fifth paragraph within Section 3.5 references Section 3.3.1.5 of the ISMP.

The second change expands the statement of objectives of the QAPIP and is acceptable.

Changes to Pages 3-7a and 3-8

These changes reflect a font change only and are acceptable.

Changes to Page 3-11 and to ISMP Section 5.2, "Control of Subcontractors"

The first change on this page corrects the citation to the current version of the QAPIP and is acceptable.

The second change deletes the reference to ISMP Section 1.3.11 for quality levels. Consistent with the discussion of Safety Criterion 7.3-1, above, this change is acceptable.

The third change deletes the reference to ISMP Section 5.2, "Control of Subcontractors" as the source of requirements for imposing QA requirements on subcontractors and replaces it with a general reference to the QAPIP. ISMP Section 5.2 contains specific direction regarding BNFL and subcontractor responsibilities and commitments. Much of the direction is related to environment, safety, and health considerations, of which portions are important to QA (e.g., periodic performance evaluation, employee training). Section 5.2 also contains specific QA commitments. **Therefore, the proposed deletion of the reference to Section 5.2 represents a decrease in commitment that is not justified by the BNFL submittal.** The deletion is also inconsistent with the BNFL-proposed QA-related changes to Section 5.2, discussed in the following paragraphs.

In addition, BNFL proposes to make the following changes to Section 5.2:

1. Modify the statement regarding subcontractors and suppliers "providing services and items Important-to-Safety" to develop and submit for approval a separate QA Plan. In addition, delete the requirement that subcontractors that are "part of the TWRS-P Project integrated team" perform their work in conformance with the QAPIP. As noted in item 3 (Subordinate QA Plans) of the analysis of Safety Criterion 7.3-2, above, BNFL now expects subcontractors to work to the BNFL QAPIP except when performing work that requires a unique quality plan. The proposed text revision does not specifically make the distinction regarding when unique quality plans are required. However, it is factually

correct and is therefore acceptable.

2. Change the general reference that controls are established to ensure purchases conform with procurement documents to a specific reference to the QAPIP as describing how purchases are controlled. This change improves the specificity of the requirement and is therefore acceptable.
3. Change the scope of audits to include both suppliers (added) and subcontractors and to reference the requirements of the QAPIP rather than those of 10 CFR 830.120. This change improves the specificity of the requirement and is therefore acceptable.

The fourth change deletes a reference to ISAR Section 3.3 as a source for details on training, qualification, and procedure development. The full scope of the requirements in ISAR Section 3.3 and the RU's analysis of deleting this reference are presented in item 3 of the analysis of Safety Criterion 7.3-2, above. Except as noted in that item, the change is acceptable.

Conclusion: The proposed deletion of reference to Section 5.2 is not acceptable. The proposed changes to the text of Section 5.2 are acceptable.

Changes to Pages 3-18 and 3-18a

The RU confirmed that these changes appropriately correct errors made during revisions of the ISMP. The changes are therefore acceptable.

Changes to Pages 13-2, 13-3, and 13-3a (References)

These changes correct one reference and add one reference. The changes are acceptable.